

REMARKS/ARGUMENTS

The Examiner's response presented in the Advisory Action dated August 29, 2006 (hereinafter Advisory Action) has been considered. The Applicant respectfully submits that the amendments to the claims place them in condition for allowance. The following discussion is included to further establish the patentability of the claims, particularly in light of the Examiner's remarks contained within the Advisory Action and the Final Office Action of June 8, 2006 (hereinafter Office Action).

Claims 1-19 and 30-36 remain pending in the application. Claims 1, 2, 6 and 11 have been amended. No claims have been added or canceled. Consideration of the pending claims and allowance of the application in view of the present amendments and remarks is respectfully requested.

Claims 1, 2, 6 and 11 have been amended. Support for the claim amendments can be found in the Applicant's Specification at, among other places, Page 15, Line 19 – Page 16, Line 2; Page 19, Line 23 – Page 21, Line 3; and Page 29, Lines 8-15.

Claims 1, 4, 7-11, 16-18, 30, 32-34, and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,704,365 to *Albrecht et al.* (hereinafter "*Albrecht*") in view of U.S. Patent No. 6,409,675 to *Turcott* (hereinafter "*Turcott*"). Claims 2, 3, 5, 6, 12, 13, 19, 31, and 35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Albrecht* in view of *Turcott*, as applied to claim 1, and further in view of U.S. Patent No. 6,792,308 to *Corbucci* (hereinafter "*Corhucchi*"). Claims 14 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Albrecht* in view of *Turcott*, as applied to claim 1, and further in view of U.S. Publication No. 2003/0032889 by *Wells* (hereinafter "*Wells*").

Among other features, Applicant's amended claims 1 and 30 recite, in varying form, separating a signal from a composite electrical signal and verifying or determining whether or not the separated signal is a cardiac electrical signal using the separated signal and non-electrophysiological cardiac source information. The combination of *Albrecht* and *Turcott* fails to teach or suggest both a separating process and a verification process as is required in Applicant's independent claims 1 and 30.

Moreover, the asserted combination fails to teach or suggest the recited verification processes that use both the separated signal and non-electrophysiological cardiac source information to verify (or determine whether or not) that the separated signal is a cardiac signal. Because the asserted combination fails to teach or suggest all features of Applicant's claims 1 and 30, as is discussed in detail hereinbelow, these claims are patentable over the asserted combination.

Albrecht teaches that a processor reduces noise in the ECG waveform by combining one or more ECG signals (primary signals) and one or more noise signals (secondary signals) that provide information about the noise content of the primary signals. *Albrecht* teaches, at column 13, lines 58-64, that:

To effectively detect alternans, processor 105 is configured to reduce the noise in the ECG waveform that it produces. Processor 105 achieves substantial reductions in the noise content of the beats of the ECG waveform by combining one or more ECG signals and one or more other signals in a way that causes the noise content of the signals to combine destructively while preserving the ECG content.

Hence, *Albrecht* teaches that its primary and secondary signals are used in a filtering process to reduce noise in the ECG signals. *Albrecht's* secondary signals are used only in this filtering process. Having been used in the filtering process, *Albrecht's* secondary signals are not used in any subsequent operation that may involve evaluating the nature of the separated signal.

Even assuming, *arguendo*, that Applicant's separating process recited in claims 1 and 30 is met by *Albrecht's* filtering process that uses both primary and secondary signals, *Albrecht* wholly fails to disclose the additional process of verifying that, or determining whether or not, the separated signal is a cardiac signal. *Albrecht's* secondary signals are clearly not described as being useful for purposes of evaluating whether or not the separated signal comprises a cardiac signal.

In the Final Office Action, the Examiner cited column 5, line 62 of *Albrecht* in support of the rejection. This portion of *Albrecht* merely states that the ECG signal is “the desired output signal.” *Albrecht*, in the lines following line 62, makes clear that this signal includes undesirable baseline noise, and as such, must be subject to further noise reduction. Respectfully, column 5, line 62 of *Albrecht* does not teach the verification of the separated signal as a cardiac signal, but only the desire (e.g., an expectation, not an identification or verification) that the output signal is an ECG signal.

Albrecht is directed to the problem of reducing noise in ECG signals. *Albrecht* fails to recognize the problem addressed by Applicant’s invention, and, therefore, fails to teach several features of Applicant’s claims 1 and 30. Applicant’s specification discloses that:

Signal separation techniques provide for separation of many individual signals from composite signals. For example, a composite signal detected on or within a patient may contain several signal components produced from a variety of signal sources, such signal components including cardiac signals, skeletal muscle movement related signals, electromagnetic interference signals, and signals of unknown origin. Signal separation techniques separate the composite signal into individual signals, but do not necessarily indicate the source of such signals. Page 26, lines 8-14 (emphasis added).

The cardiac signal may be identified among the few (e.g., two or three) largest separated signals, however examining the entirety of all candidate signals is computationally intensive. Information from a non-electrophysiologic sensor, such as those described earlier, may be used to focus the search for the cardiac signal among the candidate signals. A signal independent of cardiac electrical activity, such as an acoustic signal of cardiac heart-sounds, an accelerometer, a blood sensor, or other non-electrophysiologic source sensor, may be used to improve the detection and

classification of the cardiac signal from the separated signals. Page 29, lines 8-15 (emphasis added).

This technique (BSS or blind source separation) can separate cardiac signals from noise and artifacts in a cardiac monitoring system (either external or implantable), such as an ITCS device for example. The BSS technique is used to separate signals, and, in a primitive form, provides no information as to which signal is the cardiac signal. This information may be derived from other algorithms following the BSS signal separation operation, such as by use of a heart sound signal or other non-electrophysiologic signal. Page 32, lines 13-18 (alteration added).

Albrecht attempts to provide an ECG signal having reduced baseline noise at the skin of a patient. As was previously discussed, *Albrecht* assumes (and never questions) that the signals sensed by its surface electrodes are indeed ECG signals. The *Albrecht* disclosure does not teach or suggest that the signals sensed by the surface electrodes are anything but ECG signals. Contrary to the Examiner's comments in paragraph 11 on page 6 of the Final Office Action, Applicant's claims 1 and 30 recite use of non-electrophysiological cardiac source information to verify that the separated signal is indeed a cardiac signal.

Neither *Albrecht* nor *Turcott* teaches or suggests use of information associated with a non-electrophysiological cardiac source in the manner recited in Applicant's claims 1 and 30. In *Turcott*, various physiological sensors are used to monitor a patient's hemodynamic status. *Turcott* does not supply the many elements missing in the *Albrecht* teachings. Moreover, the asserted combination provides no motivation to combine the reference teachings in the manner suggested by the Examiner, particularly in view of the substantial omission of teachings in the primary reference, *Albrecht*, as discussed above.

In the Advisory Action, the Examiner states that "*Albrecht* 'establishes the identity of' the output signal as a cardiac signal." The Applicant respectfully disagrees that *Albrecht* establishes the identity of the output signal as a cardiac signal. As

discussed above, merely assuming that a signal is a cardiac signal involves no identifying or verification step. Because *Albrecht* does not perform a verification step that establishes the identity of the signal as a cardiac signal, and no other reference cited by the Examiner does the same, no combination of the references cited by the Examiner teaches or suggests all limitations of Applicant's independent claims 1 and 30.

For at least the reasons discussed above, Applicant's claims 1 and 30 are not rendered obvious by the combination of *Albrecht* and *Turcott*.

Dependent claims 2-19 and 31-36, which are dependent from independent claims 1 and 30, respectively, were also rejected under 35 U.S.C. §103(a) as being unpatentable over various combinations of *Albrecht*, *Turcott*, *Corbucci*, and *Wells*. While Applicant does not acquiesce with any particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 30. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." M.P.E.P. §2143.03; citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 2-19 and 31-36 are also patentable over any combination of *Albrecht*, *Turcott*, *Corbucci*, and *Wells*.

It is to be understood that Applicant does not acquiesce to Examiner's characterization of the asserted art or Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicant's claimed subject matter. Moreover, Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of Applicant's invention, officially noticed facts, and the like. Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in Applicant's pending claims and lack of motivation to combine reference teachings. Applicant,

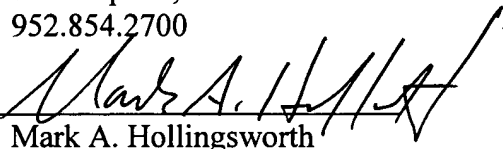
however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

In view of the remarks presented above, Applicant respectfully submits that the claims are patentable over the asserted references, timely notification of which is kindly solicited. Authorization is given to charge Deposit Account No. 50-3581 (GUID.606PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact him to discuss any issues related to this case.

Respectfully submitted,
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